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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/485,571	06/09/2000	BERNARD CALAS	19904-009	2070

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EXAMINER

KAM, CHIH MIN

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 09/24/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/485,571

Applicant(s)

CALAS ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Claims 18-34 are pending.

Applicants' amendment filed on June 25, 2002 (Paper No. 14) is acknowledged, and applicants' response has been fully considered. Claims 1-17 have been cancelled, and new claims 18-34 have been added. Thus, claims 18-34 are examined.

Oath/Declaration

2. A newly submitted oath/declaration filed on June 25, 2002 (Paper No. 15) is acknowledged.

Objection Withdrawn

3. The previous objection to specification for not conforming C.F.R.37 1.822 (d)(1) by using one letter abbreviation for amino acid sequences listed, is withdrawn in view of applicants' amendment to the specification and applicants' response at pages 15-16 (Paper No. 14).

Applicants also correctly point out that MPEP § 2429 recites "single letter amino acid abbreviations are not acceptable within the Sequence Listing but may appear elsewhere in the application".

4. The previous objection of claim 3, 5, 7 for not conforming C.F.R.37 1.822 (d) (1) by using one letter abbreviation for amino acid sequences listed, is withdrawn in view of applicants' cancellation of the claim and applicants' response at page 16 in Paper No. 14.

5. The previous objection of claim 3, 5, 7 and 8 regarding the claim containing "X", "B" "U" or "O" in the sequence, and without citing sequence identifier "SEQ ID NO:", is withdrawn

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in view of applicants' cancellation of the claim and applicants' response at page 16 in Paper No.

14.

Rejection Withdrawn

Claim Rejections - 35 USC § 101

6. The previous rejection of claims 9 and 10 under 35 U.S.C. 101, regarding recitation of a use, but without setting forth any steps in the method claim, is withdrawn in view of applicants' cancellation of the claim and applicants' response at pages 16-17 in Paper No. 14.

Claim Rejections - 35 USC § 112

7. The previous rejection of claim 1-17, under 35 U.S.C.112, first paragraph, is withdrawn in view of applicants' cancellation of the claim, and applicants' response at pages 17-18 in Paper No. 14.

8. The previous rejection of claims 1-17, under 35 U.S.C.112, second paragraph, regarding various terms, is withdrawn in view of applicants' cancellation of the claim, and applicant's response at pages 18-21 in Paper No. 14.

Claim Rejections - 35 USC § 102

9. The previous rejection of claims 1-6 and 16, under 35 U.S.C.102 (b) as being anticipated by Lehrer *et al.* (WO 96/37508), is withdrawn in view of applicants' cancellation of the claim, and applicant's response at page 22 in Paper No. 14.

10. The previous rejection of claims 1-2 and 16, under 35 U.S.C.102 (b) as being anticipated by Masuda *et al.* (Biochem. Biophys. Res. Comm. 189, 845-850 (1992)) or Tamamura *et al.* (Chem. Pharm. Bill. 41, 978-980 (1993)), is withdrawn in view of applicants' cancellation of the claim, and applicant's response at pages 23-24 in Paper No. 14.

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11. The previous rejection of claims 1-5 and 16, under 35 U.S.C.102 (a) as being anticipated by Chang *et al.* (WO 97/18826 (May 1997)) or Qu *et al.* (Infection and Immunity 65, 636-639 (February 1997)), is withdrawn in view of applicants' cancellation of the claim, and applicant's response at pages 24-25 in Paper No. 14.

Claim Objections

12. Claim 24 is objected to because of the use of the term "The method of vectoring an active substance using a peptide according to claim 18". Since claim 24 is a method claim and use the peptide recited in claim 18, the term "A method of vectoring an active substance using the peptide according to claim 18" should be used.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claim 18, 19 and 24-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 18, 19 and 24-34 are indefinite because of the use of the term "derived from". The term "derived from" renders the claim indefinite, it is unclear what amino acid sequence the peptide has as compared to the parent compound, the antibiotic peptide or its analog. Use of the term "obtained from" is suggested. Claim 25 is also indefinite because of the term "a β -stranded antibiotic or an analog thereof", it is not clear what compound is as to "a β -stranded antibiotic".

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Claims 19, 24 and 26-34 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

In response, applicants indicate “the isolated peptide derived from an antibiotic peptide or an analog thereof” (claim 18) means the isolated peptide has the modification on cysteine residues of the antibiotic peptide such that the isolated peptide is devoid of disulfide bond as shown at page 8, lines 1-8 of the specification (page 19 of the response). The argument is not persuasive because the term “derived from” indicates various changes can be made on the parent compound to yield the resulting peptide, therefore, it is not clear what amino acid sequence the peptide derived from parent compound has.

14. Claims 20-34 are indefinite because of the use of the term “an active substance” or “a signal agent”. The term “an active substance” or “a signal agent” renders the claim indefinite, it is unclear what the active substance is, what function the active substance has, which compound is intended as a signal agent, and what the signal agent is used for. Claims 20-34 are also indefinite because of the use of the term “a particular cell compartment, a particular cell type or a particular organ”, it is not clear how the active substance coupled with the peptide can target at a particular cell compartment, a particular cell type or a particular organ. Claims 21-24 and 26-34 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

In response, applicants indicate the terms “an active substance” (page 11, line 7 –page 12, line 13) and “a signal agent” (page 12, line 27-page 13, line 7) are defined in the specification (page 21 of the response). The argument is not persuasive because the specification indicates certain compounds can be used as “an active substance” or “a signal agent”, however, the

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limitation is not recited in the claim, it is not clear what compound “an active substance” or “a signal agent” is.

15. Claim 23 and 28 are indefinite because of the term “such as”, the phrase “such as” renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). It is also not clear in the claim whether the amino acid is natural or not as to “an amino acid, which may or may not be natural”.

16. Claim 26 is an improper dependent claim because it claims the compound according to claim 24, which is a method claim. Claim 26 recites the limitation “said linear peptide (A)” in line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 31 is included in the rejection because it is dependent on a rejected claim and does not correct the deficiency of the claim from which it depends.

17. Claim 33 is an improper dependent claim because it claims a pharmaceutical composition comprising at least one compound of formula (IV) according to claim 24, which is a method claim. Claim 33 recites the limitation “compound of formula (IV)” in line 2. There is insufficient antecedent basis for this limitation in the claim.

Conclusions

18. No claims are allowed.

Art of record

The claims are directed to a peptide obtained from antibiotic peptides or analogs, where the peptide has the sequence of SEQ ID NO:23 and is devoid of disulfide bond; a compound of the formula (IV), $(Y)_n-(A)-(Z)_m$, wherein A is a linear peptide obtained from a β -stranded antibiotic peptide or an analog, wherein the linear peptide is devoid of disulfide bond, Z is an

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active substance, and Y is signal agent; and a method for vectoring an active substance to a target cell or organ using a β -stranded antibiotic peptide or an analog, wherein the linear peptide is devoid of disulfide bond, it appears the claimed invention is free of prior art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

Karen Cochrane Carlson
KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER

September 20, 2002